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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/401,636 09/22/99 HELLMAN

L 10223/006001

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EXAMINER

EWOLDT, G

ART UNIT

PAPER NUMBER

1644

16

DATE MAILED:

06/28/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/401,636

Applicant(s)

Hellman

Examiner

G. R. Ewoldt

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on May 1, 2001
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 2, 4-11, and 25-54 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4-11, and 25-54 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 20) ☐ Other:

DETAILED ACTION

1. The request filed on 5/01/01 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/401,636 is acceptable and a CPA has been established. An action on the CPA follows.

2. Claims 1-2, 4-11, and 25-54 are pending and being acted upon.

3. In view of Applicant's amendment and response, filed 5/01/01, only the following rejections remain.

4. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-2, 4-11, and 25-54 stand rejected under 35 U.S.C. 112, first paragraph, for the reasons of record set forth previously in Paper No. 9, mailed 7/3/00 and Paper No. 13, mailed 1/02/01.

Applicant's arguments, filed 5/01/01, have been fully considered but they are not persuasive. Applicant argues that the newly amended Claim 1 now recites that the non-self "portions" of the claimed constructs consist essentially of IgE CH2 and CH4 domains and that said amendment, while unnecessary, further enables the claims. However, the claims still do not recite a specific piece of the CH3 domain. While the prior art and the instant specification may disagree on the specific portion of the CH3 domain required for Fc binding, both teach that some part of said domain is required. Thus, claims reciting merely a "portion" of CH3 are not enabled because said "portion" is not defined and could include as little as a single amino acid of CH3 which would be insufficient to generate the claimed anti-self response.

6. The following are New Grounds for Rejection.

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1, 4-7, and 10-11 stand rejected under 35 U.S.C. 102(b) as being anticipated by Nissim et al. (1995)

Nissim et al. teaches an immunogenic polypeptide comprising self and non-self domains (portions) of IgE. The reference teaches a peptide of the composition humanCH2 - mouseCH3 - humanCH4 (see particularly page 128, Table 1, CHM3). Said peptide comprises at least a portion of an IgE CH3 domain and also consists essentially of an IgE CH2 and CH4 domain. Said peptide further lacks a self CH2 domain when the "self" is a mouse. As a composition can not be separated from its inherent properties, Claim 4 is included in the rejection because it is an inherent property that the referenced IgE polypeptide is capable of dimerizing. Likewise, Claim 11 is included in the rejection because the polypeptide of the prior art would be capable of generating an anti-self IgE polyclonal response as does the polypeptide disclosed in the specification.

The reference clearly anticipates the claimed invention.

9. Claims 1-2, 45-11, 25-40, and 48-54 are rejected under 35 U.S.C. § 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed. This is a new matter rejection.

The specification and the claims as originally filed do not provide support for the invention as now claimed, specifically:

A) "An immunogenic polypeptide ... wherein said non-self IgE portion consists essentially of a CH2 domain," (claim 1),

B) "An immunogenic polypeptide ... wherein said immunogenic polypeptide lacks a CH1 domain of IgE," (claim 25).

C) "An immunogenic polypeptide ... wherein said non-self IgE portion consists essentially of an N terminal portion," (claim 33),

D) "An polypeptide ... wherein said polypeptide lacks light chain Ig sequences," (claim 48).

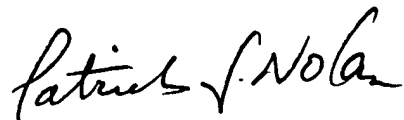
Applicant's amendment, filed 5/01/01, asserts that no new matter has been added and indicates that support for the amendment of Claim 1 and the additional new claims can be found in Figure 2. However, Figure 2 does not provide support for generic, or subgeneric, claims encompassing the newly recited limitations. In *Gentry Gallery, Inc. v. The Berkline Corp.*, 134 F.3d 1473, 1479-80, 45 USPQ2d 1498, 1503 (Fed. Cir. 1998), the court acknowledged that while a claim may be broader than the specific embodiment disclosed in the specification, the "claims may be no broader than the supporting disclosure." Thus, a narrow disclosure will limit claim breadth.

10. No claim is allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (703) 308-9805. The examiner can normally be reached Monday through Thursday and alternate Fridays from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

G.R. Ewoldt, Ph.D.
Patent Examiner
Technology Center 1600
June 21, 2001



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